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EXAMINER BERTOGGIO, VALARIE E				
ART UNIT			PAPER NUMBER	
1632				

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,896

Applicant(s)

CAMPBELL ET AL.

Examiner

Valarie Bertoglio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16, 17, 22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 17, 22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's amendment filed 06/24/2004 has been entered. Claims 1-7,10,14,16,17,22 and 24 have been amended. Claims 15,18-21 and 23 have been cancelled. Claims 27 and 28 have been added. Claims 1-14, 16, 17, 22 and 24-28 are pending and are currently under consideration.

#### ***Double Patenting***

Claims 1-4, 7-9, 11-14,16 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 6,004,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method of increasing weight in poultry using an animal supplement comprising animal plasma. Therefore the claims of '576 anticipate the instant claims.

The methods of claims 1-4 and 6-8 of '576 encompass methods of increasing weight gain of an animal comprising administering to animals a supplement comprising spray dried animal plasma wherein the plasma is formed into particles ranging in size of 100-2000 microns. Claims 1-4 and 6-8 of '576 anticipate claims 1-4 and 7-9 of the instant invention as they are drawn to methods of increasing live weight of poultry, which is an animal, by supplementing feed with spray dried animal plasma wherein the particle size of the animal plasma is between 50 and 2000 microns (claims 1-4 and 7-9). While claim 1 of '576 is drawn to increasing the weight of any species of animal, claim 7 of '576 limits the animal species to those including chicken, duck and turkey, which are poultry as claimed in claim 14 of the instant invention. '576 claims also limit the animal plasma to 0-15% of animal rations (claim 3) which is "up to 15% by weight" as

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specified by claim 3 of the instant invention. Claim 8 of '576 specifies that the dried animal plasma is isolated from a number of species including porcine and bovine which are livestock as claimed in claims 11 and 12 of the instant invention. Claim 4 of '576 specifies administering the supplement in the first 10 weeks of life, which constitutes newly hatched poultry as in claim 14 of the instant invention.

The claims of '576 do not specifically recite that the methods preferentially increase the yield of white meat from the poultry by about 6-8% by weight as specified by claims 1,16 and 17.

Applicant has responded to the previous double patenting rejection by amending claim 1 to include the limitations of claim 16, which was not rejected in the previous office action, to recite that the method preferentially increases the yield of white meat of the poultry.

However, upon further consideration, since it does not appear that the methods are different or that the plasma administered is structurally or compositionally different, then it is inherent that the methods of '576, being the same as those of the instant invention, will preferentially increase the yield of white meat from the poultry. The preferential increase in white meat as claimed in the instant invention is merely an unrecognized property of the patented methods of '576.

Therefore, the double patenting rejection is maintained as it applies to claims 1-4, 7-9, 11-14,16 and 17.

***Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16, 17, 22 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claims 1-7, 14, 16, 17 contains the term "composition" which is new matter. Literal support for this terminology is not found in the specification. The specification refers to the spray-dried plasma as "the plasma protein composition"; see, for example, page 8, line 20 and line 23. Claims 8-13, 17 and 27 depend from claim 1.

Claims 1, 16 and 17 contain the phrase "preferentially increases the yield of white meat from the poultry". Literal support for this terminology is not found in the specification. The specification has taught preferential increases in the yield of breast meat at the expense of leg and thigh meat. Claims 2-13, 17 and 27 depend from claim 1.

The phrases "up to about 0.05-3.0%" and "up to about 0.1-1.5%" in claims 5 and 6 respectively, are new matter. The phrases "about 0.05 to about 3.0%" and "about 0.1 to about 1.5%" in claims 22 and 24, respectively are new matter. Literal support for this terminology is not found in the specification. The specification teaches that the plasma protein composition should be in the water in a concentration from "about 0.05-3.0%" and preferably "about 0.1-

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1.5%” (refer to page 8, lines 20-25). Claims 25,26 and 28 depend from claim 22.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 1-14, 16, 17,22 and 24-28 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

The rejection of claim 10 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record as set forth on pages 5-6 of the

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previous office action mailed 03/24/2004. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's arguments have been fully considered and are found partially persuasive as set forth below.

Applicant has amended claim 10 such that it no longer requires obtaining plasma from transgenic plants and microorganisms. Applicant has also argued that the claim is now enabled because the claim does not require that the transgene in the transgenic animal make the plasma more effective over that of a non-transgenic animal used in the claimed methods (see Applicant's remarks, page 8, lines 21-24).

In response, the rejection on the grounds that the specification fails to enable the transgenic plant and microorganism of the claim is withdrawn in light of Applicant's amendment to the claim. However, with respect to the claimed transgenic animal, the rejection is maintained. The specification contemplates using plasma from natural animal sources or from recombinant means. The specification fails to contemplate using a transgenic animal as a natural source of plasma. Therefore, because the specification fails to support using a transgenic animal as a natural source of plasma, the claim encompasses and is interpreted as a method wherein a transgenic animal is used as a source of recombinant plasma to increase the live weight of poultry. As set forth in the previous office action, the specification fails to overcome the unpredictability associated with the art of making transgenic animals, requiring undue experimentation to carry out the claimed method using a transgenic animal.

***Claim Rejections - 35 USC § 112-2nd paragraph***

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in light of Applicant's amendments to the claims. However, a new grounds of rejection based on amendment of the claims appears below.

Claims 1-14,16,17,22,27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14,16 and 17 are unclear because it is not clear what the term "composition" is referring to. For example, the composition could be referring to the spray-dried animal plasma protein composition as set forth in the specification on page 8, line 23. Or, for example, the composition could be referring to a composition comprising animal plasma such as feed or water mixed with spray-dried animal plasma protein. Claims 2-14 and 17 depend from claim 1.

Claims 5,6,22,24 are unclear because of the phrases "whereby the composition comprises up to about 0.05-3.0% by weight of water" (claim 5), "whereby the composition comprises up to about 0.1-1.5% by weight of water" (claim 6), "whereby the plasma product comprises about 0.05 to about 3.0% by weight of water" (claim 22) and "whereby the plasma product comprises about 0.1-1.5% by weight of water". It is unclear if the composition and the plasma product referred to by the claims are referring to the water mixed with spray dried animal plasma or spray dried animal plasma alone. Therefore, for example, it is unclear what makes up 0.05-3.0% by weight of water or if water makes up 0.05-3.0% by weight of the composition.



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Claim 22 recites the limitation "the plasma product" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is unclear what product "the plasma product" is referring to. It is not clear if "the plasma product" is the "the plasma water product" of the preamble or the "animal plasma" of line 4.

Claims 27 and 28 are unclear because the metes and bounds of the phrase "substantially free of fibrinogen" are indefinite. The phrase is non-limiting as the amount of fibrinogen that will cause clotting is concentration dependent and therefore dependent upon the amount and nature of the solution. Furthermore, With respect to claim 27, the claim is not limited to a liquid as claim 1 encompasses a dry composition. It is unclear how the limitation of "substantially free of fibrinogen" applies to a solid composition in light of the teachings in the specification with respect to the phrase (refer to page 6).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-4,7-9,11-14,16 and 17 under 35 U.S.C. 102(b) as being anticipated by Weaver (US 6,004,576, 1999) is maintained and newly applied to claims 16 and 17 as set forth below. Applicant's arguments have been thoroughly considered and are found partially persuasive.

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Applicant has amended claim 22 such that claims 22,25 and 26 required specific weight composition of animal plasma in water that is not specifically disclosed by Weaver and therefore the rejection is withdrawn with respect to claims 22,25 and 26.

Applicant has also responded to the previous rejection set forth on pages 8-9 of the previous office action, mailed 03/24/2004 by amending claim 1 to include the limitations of claim 16, which was not rejected in the previous office action, to recite that the method preferentially increases the yield of white meat of the poultry.

However, upon further consideration, since it does not appear that the methods are different or that the plasma administered is structurally or compositionally different, then it is an inherent property of the methods taught by Weaver, the methods being the same as those of the instant invention, that the methods will preferentially increase the yield of white meat from the poultry. The preferential increase in white meat as claimed in the instant invention is merely an unrecognized property of the patented methods of Weaver. Therefore, for these reasons, Weaver applies to amended claim 1 and claims 16 and 17.

Furthermore, the rejection is also applied to claim 10. Claim 10 requires that the source of plasma be a transgenic animal. As set forth by Applicant, the pending claims do not recite that the transgene causes the plasma to be more effective. As such, the transgenic animal is merely a source of animal plasma that is made obvious by Weaver.

Thus, the teachings of Weaver anticipate all of the claim limitations.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejections of claims 1-7,10,11,13,14,16-18,22, and 24-26 under 35 U.S.C. 103(a) as obvious over Adalsteinsson (US 6,086,878, effective filing date August 21, 1997) is maintained. The rejection under 35 U.S.C. 103(a) is maintained and newly applied to claims 5,6,16,17 and 24 for reasons presented in the office action mailed March 24, 2004 and for further reasons set forth below.

As set forth on pages 9-10 of the office action mailed 03/24/2004, Adalsteinsson taught a method for increasing the live weight of poultry using spray dried egg yolk or plasma as a supplement in feed and water.

Applicant has amended claims to include the limitations that the methods preferentially increase the yield of white meat from the poultry and that the composition (claims 1 and 16), as a water supplement comprises either up to about 0.05-3.0% by weight of the water or up to about 0.1-1.5% by weight of the water (claims 5,6,22,24-26). Applicant has argues that these limitations are not taught by Adalsteinsson and therefore, the claims are no longer anticipated.

However, as set forth in the rejection under 35 USC 102(b) above, since it does not appear that the methods are different or that the plasma administered would be structurally or compositionally different than that of Adalsteinsson, then it is an inherent property of the methods taught by Weaver, being the same as those of the instant invention, that the methods will preferentially increase the yield of white meat from the poultry. The preferential increase in

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white meat as claimed in the instant invention is merely an unrecognized property of the methods of Adalsteinsson.

With respect to the claim limitation set forth in claims 5,6,22 and 24-26 limiting the percent composition of plasma in the water, it would be obvious to use the claimed percent compositions as it would require only routine optimization for the skilled artisan to arrive at these limitations to obtain a water comprising the plasma composition that maximally dissolves the composition, offers benefit to the poultry and does not exhibit a taste that deters consumption.

Furthermore, the rejection is also applied to claim 10. Claim 10 requires that the source of plasma be a transgenic animal. As set forth by Applicant, the pending claims do not recite that the transgene causes the plasma to be more effective. As such, the transgenic animal is merely an obvious source of animal plasma that does not materially differ from that of a non-transgenic animal.

Thus, the claimed invention is clearly *prima facie* obvious in the absence of evidence to the contrary.

### ***Claim Rejections - 35 USC § 102/103***

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Weaver (US 6,004,576, 1999).

Claims 1 is rejected under 35 USC 102(b) as set forth above. Claim 10 requires that the source of plasma be a transgenic animal. Applicant has made it of record that the pending claims do not recite that the transgene causes the plasma to be more effective and the transgenic animal

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of claim 10 is a source of animal plasma in the same sense as a non-transgenic animal.

Therefore, the limitation requiring that the animal be transgenic does not provide a patentable distinction between claims 1 and 10.

In the alternative the animals used as a source of plasma as taught by Weaver render the transgenic animals of claim 10 obvious because there is no disclosed, discernable patentable distinction between the methods of Weaver, using a non-transgenic animal and those of claim 10, requiring a transgenic animal because, as set forth by Applicant, the transgene or transgenes of the transgenic animal confer to increased effectiveness on the method. Thus at the time of the present invention, the ordinary artisan would have found the claimed methods using a transgenic animal obvious over the same methods using a non-transgenic animal as disclosed by Weaver.

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***Conclusion***

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Fri 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Valarie Bertoglio  
Examiner  
Art Unit 1632

*Jon Waitach*  
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